

FOX ROTHSCHILD LLP

By: Karen A. Confoy, Esq.
Princeton Pike Corporate Center
997 Lenox Drive, Building 3
Lawrenceville, NJ 08648
Telephone: (609) 896-3600
Facsimile: (609) 896-1469
Attorneys for Defendants
Merck Sharp & Dohme Corp. and Merck & Co., Inc.

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE: FOSAMAX (ALENDRONATE
SODIUM) PRODUCTS LIABILITY
LITIGATION**

MDL No. 2243
Master Docket No. 08-08(JAP)(LHG)

**THIS DOCUMENT RELATES TO:
ALL CASES**

Document Filed Electronically

**ORDER GRANTING MERCK'S MOTION FOR ENTRY OF AN ORDER PURSUANT
TO L. CIV. R. 5.3 DIRECTING THE CLERK TO SEAL MATERIALS CONTAINING
INFORMATION THAT HAS BEEN DESIGNATED AS CONFIDENTIAL**

THIS MATTER having been opened to the Court by Defendants Merck Sharp & Dohme Corp. and Merck & Co., Inc. ("Merck"), through counsel, Fox Rothschild LLP, for entry of an Order granting Merck's Motion pursuant to L. Civ. R. 5.3(c) directing the Clerk to seal materials containing information that has been designated as confidential; and on notice to Plaintiffs, through counsel; and the Court, having considered the papers submitted in support of the Motion, hereby makes the following Findings of Fact and Conclusions of Law:

FINDINGS OF FACT

1. Merck filed the materials identified in Exhibit A, which have been designated by either Merck or Plaintiffs as containing Confidential Information during the course of discovery (collectively the "Materials").

2. Merck filed the documents identified in Exhibit B temporarily under seal but has determined that the information contained in these documents is no longer confidential.

3. The Materials contain and/or reference sensitive information, including information generally concerning Merck's proprietary and/or commercially sensitive internal business practices, databases, and communications with the Food and Drug Administration, and private and sensitive medical information pertaining to Plaintiff Barbara Gaynor. The parties have agreed to maintain the confidentiality of certain information and have therefore entered into a Stipulated Discovery Confidentiality Order ("DCO"), which governs the parties' use and handling of this information.

4. The DCO was filed with the Court on January 11, 2013 (See ECF 2083, Master Docket No. 08-08).

5. Pursuant to L. Civ. R. 5.3(c) and Paragraph 27 of the DCO, Merck has moved to file the Materials under seal.

6. There is no less restrictive alternative to the filing of the Materials under seal. Only the Materials will be restricted from public access, which is a necessary compromise in a litigation involving private litigants.

7. Merck has a legitimate interest in sealing the Materials, because the Materials have been designated by either Merck or Plaintiffs as containing Confidential Information, and because Paragraph 27 of the DCO requires that, to the extent the parties file Confidential Information with the Court, such Confidential Information must be filed under seal, and the filing party must file a supporting motion to seal the Confidential Information in accordance with L. Civ. R. 5.3.

8. A clearly defined and serious injury will result to Merck if it is not permitted to file the Materials under seal. Without leave to file the Materials under seal, Merck will be unable to rely upon the Materials, and Merck will be unfairly limited in its ability to effectively advocate its position. Merck will also suffer a clearly defined and serious injury if its Confidential Information is publicly disclosed and made available to its competitors, who could use it unfairly to their advantage.

CONCLUSIONS OF LAW

1. The Court Finds that Merck filed the Materials identified in Exhibit A, which have been designated by either Merck or Plaintiffs as containing Confidential Information during the course of discovery.

2. The Court finds that Merck filed the documents identified in Exhibit B temporarily under seal but has determined that the information contained in these documents is no longer confidential.

3. The Materials contain and/or reference sensitive information, including information generally concerning Merck's proprietary and/or commercially sensitive internal business practices, databases, and communications with the Food and Drug Administration, and private and sensitive medical and other information pertaining to Plaintiff Barbara Gaynor. The parties have agreed to maintain the confidentiality certain information and have therefore entered into a DCO, which governs the parties' use and handling of this information. (See ECF 2083, Master Docket No. 08-08).

2. The DCO was filed with the Court on January 11, 2013.

3. Pursuant to L. Civ. R. 5.3(c) and Paragraph 27 of the DCO, Merck has moved to file the Materials under seal.

4. There is no less restrictive alternative to the filing of the Materials under seal. Only the Materials will be restricted from public access, which is a necessary compromise in a litigation involving private litigants.

5. Merck has a legitimate interest in sealing the Materials, because the Materials have been designated by either Merck or Plaintiffs as containing Confidential Information, and because Paragraph 27 of the DCO requires that, to the extent the parties file Confidential Information with the Court, such Confidential Information must be filed under seal, and the filing party must file a supporting motion to seal the Confidential Information in accordance with L. Civ. R. 5.3.

6. A clearly defined and serious injury will result to Merck if it is not permitted to file the Materials under seal. Without leave to file the Materials under seal, Merck will be unable to rely upon the Materials, and Merck will be unfairly limited in its ability to effectively advocate its position. Merck will suffer a clearly defined and serious injury if its Confidential Information is publicly disclosed and made available to its competitors, who could use it unfairly to their advantage.

7. Although there is a presumptive right of public access to judicial proceedings and records, district courts have recognized that such right is not absolute; and further, that the presumption may be rebutted. In re Cendant Corp., 260 F.3d 183, 194 (3d Cir. 2001).

8. To overcome the presumption of openness, and to justify the entry of an order sealing judicial records, the moving party must demonstrate: (1) a substantial and compelling interest in confidentiality and (2) that divulgence would work a clearly defined and serious injury to the party seeking disclosure. Pansy v. Borough of Stroudsburg, 23 F.3d 772, 787 (3d Cir. 1994).

9. Once the movant establishes the foregoing two elements, a district court will engage in a balancing process, pursuant to which the court will weigh the common law presumption of access against those factors that mitigate against access. In re Cendant Corp., 260 F.3d at 194; see also Republic of Philippines v. Westinghouse Elec. Corp., 949 F.3d 653, 662 (3d Cir. 1991) (holding that a presumption of access alone does not end the court’s inquiry as the right to access judicial records is not absolute; indeed, a “presumption is just that” and may therefore be rebutted).

10. The Court concludes that the articulated bases for sealing the unredacted Materials weighs against any presumptive right of public access, and the unredacted Materials must therefore be sealed as a matter of law.

IT IS on this ____ day of _____ 2015;

ORDERED that Merck’s Motion be and hereby is **GRANTED**; and

IT IS FURTHER ORDERED that the Clerk be and hereby is directed to permanently seal the following Docket Entries, including all attachments thereto, as set forth in Exhibit A:

- ECF 2859;
- ECF 3034;
- ECF 3037;
- ECF 3160;
- ECF 3161;
- ECF 3823; and
- ECF 3824.

IT IS FURTHER ORDERED that Merck be and hereby is directed to publicly file the following documents, as set forth in Exhibit B, within _____ days of the date of entry of this Order:

- ECF 2859-3, Exhibit 4;
- ECF 2859-4, Exhibit 5;
- ECF 3034, Exhibit A-2;
- ECF 3037-3, Exhibit 27;
- ECF 3037-6, Exhibit 39;
- ECF 3037-20, Exhibit 66;
- ECF 3161, Exhibit 6; and
- ECF 3161-1, Exhibit 12.

HONORABLE LOIS H. GOODMAN
UNITED STATES MAGISTRATE JUDGE

EXHIBIT A

Below is a full list of the materials Merck Sharp & Dohme Corp. and Merck & Co., Inc. request that the Court order the Clerk to seal pursuant to L. Civ. R. 5.3(c). The materials contain and/or reference sensitive information, including information generally concerning (1) Merck's proprietary and/or commercially sensitive internal business practices, databases, and communications with the Food and Drug Administration, and (2) private and sensitive medical and other information pertaining to Plaintiff Barbara Gaynor. The parties have agreed to maintain the confidentiality of certain information and have therefore entered into a Discovery Confidentiality Order, which governs the parties' use and handling of this information.

Docket Item	Materials to be Kept Confidential	Legitimate Private or Public Interests Which Warrant Confidentiality	Serious Injury That Would Result Should Order Not Be Entered
Exhibits to the Declaration of Karen A. Confoy (ECF No. 2858) in Support of Merck's Application for an Order to Show Cause (ECF No. 2857)			
2859	<p>Exhibit 1: E-mail from FDA to Merck, dated 6/13/2008.</p> <p>This Exhibit was filed under seal pursuant to the June 17, 2013 Sealing Order (ECF No. 232, Civil Action No. 11-cv-05304).</p> <p>This document was Exhibit 4 to Merck's Motion for Summary Judgment Based Upon Federal Preemption (ECF No. 25, Civil Action No. 11-cv-05304), filed January 15, 2013.</p>	Merck's commercially sensitive communications with the FDA	Merck would be irreparably harmed if its confidential communications with the FDA, which includes confidential research data, were available to the public. Its competitors could use the confidential information contained therein to unfairly compete with Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in its Application for an Order to Show Cause.

2859-1	<p>Exhibit 2: Letter from Merck to FDA re: Response to Information Request, dated 7/18/2008.</p> <p>This Exhibit was filed under seal pursuant to the June 17, 2013 Sealing Order (ECF No. 232, Civil Action No. 11-cv-05304).</p> <p>This document was Exhibit 6 to Merck's Motion for Summary Judgment Based Upon Federal Preemption (ECF No. 25, Civil Action No. 11-cv-05304), filed January 15, 2013.</p>	Merck's commercially sensitive communications with the FDA	<p>Merck would be irreparably harmed if its confidential communications with the FDA, which includes confidential research data, were available to the public. Its competitors could use the confidential information contained therein to unfairly compete with Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in its Application for an Order to Show Cause.</p>
2859-2	<p>Exhibit 3: Letter from Merck to FDA re: Prior Approval Supplement, dated 9/15/2008.</p> <p>This Exhibit was filed under seal pursuant to the June 17, 2013 Sealing Order (ECF No. 232, Civil Action No. 11-cv-05304).</p> <p>This document was Exhibit 8 to Merck's Motion for Summary Judgment Based Upon Federal Preemption (ECF No. 25, Civil Action No. 11-cv-05304), filed January 15, 2013.</p>	Merck's commercially sensitive communications with the FDA	<p>Merck would be irreparably harmed if its confidential communications with the FDA, which includes confidential research data, were available to the public. Its competitors could use the confidential information contained therein to unfairly compete with Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in its Application for an Order to Show Cause.</p>

Docket Item	Materials to be Kept Confidential	Legitimate Private or Public Interests Which Warrant Confidentiality	Serious Injury That Would Result Should Order Not Be Entered
Exhibits to Declaration of David J. Heubeck (ECF No. 3033) in Support of Merck's Reply (ECF No. 3031) to Plaintiffs' Procedural Brief (ECF No. 2995-3) in Response to the Court's Order to Show Cause (ECF No. 2985)			
3034	Exhibit A-3: E-mail to members of Merck's Data Mining Initiative Committee attaching meeting agenda and data mining proposal dated 1/24/2005	Merck's proprietary and/or commercially sensitive internal business practices and databases	Merck would be irreparably harmed if its proprietary and commercially sensitive internal business practices and databases were made public. Merck's competitors could use this information to unfairly compete against Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Reply to Plaintiffs' Procedural Brief in Response to the Court's Order to Show Cause
3034	Exhibit A-4: Document relating to a second phase of Merck's data mining exploration dated 12/20/2005	Merck's proprietary and/or commercially sensitive internal business practices and databases	Merck would be irreparably harmed if its proprietary and commercially sensitive internal business practices and databases were made public. Merck's competitors could use this information to unfairly compete against Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Reply to Plaintiffs' Procedural Brief in Response to the Court's Order to Show Cause

3034	Exhibit A-5: Document titled "Signal Management Implementation Guidelines," which identifies members of Merck's Data Mining Committee dated 9/16/2006	Merck's proprietary and/or commercially sensitive internal business practices and databases	Merck would be irreparably harmed if its proprietary and commercially sensitive internal business practices and databases were made public. Merck's competitors could use this information to unfairly compete against Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Reply to Plaintiffs' Procedural Brief in Response to the Court's Order to Show Cause
3034	Exhibit A-6: E-mail to members of Merck's Data Mining Committee attaching a meeting agenda and related documents dated 8/23/2007	Merck's proprietary and/or commercially sensitive internal business practices and databases	Merck would be irreparably harmed if its proprietary and commercially sensitive internal business practices and databases were made public. Merck's competitors could use this information to unfairly compete against Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Reply to Plaintiffs' Procedural Brief in Response to the Court's Order to Show Cause
3034-1	Exhibit A-12: 2003 Clinical Risk Management and WPS&E Pilot Plan for the Pharmacoepidemiology (PEPI) Unit	Merck's proprietary and/or commercially sensitive internal business practices and databases	Merck would be irreparably harmed if its proprietary and commercially sensitive internal business practices and databases were made public. Merck's competitors could use this information to unfairly compete against Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its reply to Plaintiffs' Procedural Brief in Response to the Court's Order to Show Cause

Docket Item	Materials to be Kept Confidential	Legitimate Private or Public Interests Which Warrant Confidentiality	Serious Injury That Would Result Should Order Not Be Entered
Exhibits to Declaration of Karen Confoy (ECF No. 3035) in Support of Merck's Replies (ECF Nos. 3030-3031) to Plaintiffs' Briefs in Response to the Court's Order to Show Cause (ECF No. 2895) and in Support of Merck's Preliminary Statement of Facts (ECF No. 3032)			
3037	Exhibit 1: Letter from Merck to the FDA, dated 3/10/1992	Merck's commercially sensitive communications with the FDA	Merck would be irreparably harmed if its confidential communications with the FDA, which includes confidential research data, were available to the public. Its competitors could use the confidential information contained therein to unfairly compete with Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts
3037-1	Exhibit 12: An excerpt from the Clinical Study Report of Protocol No. 051, dated 6/25/1998	Merck's proprietary and/or commercially sensitive internal business practices and databases	Merck would be irreparably harmed if its proprietary and commercially sensitive internal business practices and databases were made public. Merck's competitors could use this information to unfairly compete against Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts

Docket Item	Materials to be Kept Confidential	Legitimate Private or Public Interests Which Warrant Confidentiality	Serious Injury That Would Result Should Order Not Be Entered
3037-2	Exhibit 18: Excerpts from Merck's 2001 Annual Report regarding Fosamax	Merck's proprietary and/or commercially sensitive internal business practices and databases	Merck would be irreparably harmed if its proprietary and commercially sensitive internal business practices and databases were made public. Merck's competitors could use this information to unfairly compete against Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts
3037-3	Exhibit 21: WAES Adverse Experience Report 0310USA02081, first sent to the FDA on 11/10/2003	Nonpublic and unverified information including medical information and personal identifiers regarding non-parties to this litigation for which there is no release for disclosure	Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts
3037-3	Exhibit 22: WAES Adverse Experience Report 0310USA02248, first sent to the FDA on 11/14/2003	Nonpublic and unverified information including medical information and personal identifiers regarding non-parties to this litigation for which there is no release for disclosure	Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts

Docket Item	Materials to be Kept Confidential	Legitimate Private or Public Interests Which Warrant Confidentiality	Serious Injury That Would Result Should Order Not Be Entered
3037-3	Exhibit 23: WAES Adverse Experience Report 0311USA00975, first sent to the FDA on 11/20/2003	Nonpublic and unverified information including medical information and personal identifiers regarding non-parties to this litigation for which there is no release for disclosure	Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts
3037-3	Exhibit 24: WAES Adverse Experience Report 0311USA00976, first sent to the FDA on 11/20/2003	Nonpublic and unverified information including medical information and personal identifiers regarding non-parties to this litigation for which there is no release for disclosure	Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts
3037-3	Exhibit 25: WAES Adverse Experience Report 0311USA00974, first sent to the FDA on 11/20/2003	Nonpublic and unverified information including medical information and personal identifiers regarding non-parties to this litigation for which there is no release for disclosure	Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts

Docket Item	Materials to be Kept Confidential	Legitimate Private or Public Interests Which Warrant Confidentiality	Serious Injury That Would Result Should Order Not Be Entered
3037-3	Exhibit 26: WAES Adverse Experience Report 0311USA00841, first sent to the FDA on 11/20/2003	Nonpublic and unverified information including medical information and personal identifiers regarding non-parties to this litigation for which there is no release for disclosure	Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts
3037-3	Exhibit 28: WAES Adverse Experience Report 0403USA00626, first sent to the FDA on 3/12/2004	Nonpublic and unverified information including medical information and personal identifiers regarding non-parties to this litigation for which there is no release for disclosure	Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts
3037-3	Exhibit 29: WAES Adverse Experience Report 0403USA02294, first sent to the FDA on 4/2/2004	Nonpublic and unverified information including medical information and personal identifiers regarding non-parties to this litigation for which there is no release for disclosure	Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts

Docket Item	Materials to be Kept Confidential	Legitimate Private or Public Interests Which Warrant Confidentiality	Serious Injury That Would Result Should Order Not Be Entered
3037-4	Exhibit 31: WAES Adverse Experience Report 0411USA00196, first sent to the FDA on 11/9/2004	Nonpublic and unverified information including medical information and personal identifiers regarding non-parties to this litigation for which there is no release for disclosure	Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts
3037-5	Exhibit 35: Excerpt from the 2005 Periodic Safety Update Report, dated 9/1/2005	Merck's proprietary and/or commercially sensitive internal business practices and databases	Merck would be irreparably harmed if its proprietary and commercially sensitive internal business practices and databases were made public. Merck's competitors could use this information to unfairly compete against Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts

Docket Item	Materials to be Kept Confidential	Legitimate Private or Public Interests Which Warrant Confidentiality	Serious Injury That Would Result Should Order Not Be Entered
3037-6	Exhibit 37: Clinical Report for Fosamax: Summary of Reports of Heart Failure in Patients Receiving Alendronate, dated 10/12/2005	Merck's proprietary and/or commercially sensitive internal business practices and databases	Merck would be irreparably harmed if its proprietary and commercially sensitive internal business practices and databases were made public. Merck's competitors could use this information to unfairly compete against Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts
3037-6	Exhibit 38: Excerpts from Merck's 2005 Annual Report regarding Fosamax, dated 11/21/2005	Merck's proprietary and/or commercially sensitive internal business practices and databases	Merck would be irreparably harmed if its proprietary and commercially sensitive internal business practices and databases were made public. Merck's competitors could use this information to unfairly compete against Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts

Docket Item	Materials to be Kept Confidential	Legitimate Private or Public Interests Which Warrant Confidentiality	Serious Injury That Would Result Should Order Not Be Entered
3037-6	Exhibit 40: Annual IND Progress Report, dated 10/26/2006	Merck's commercially sensitive communications with the FDA	Merck would be irreparably harmed if its confidential communications with the FDA, which includes confidential research data, were available to the public. Its competitors could use the confidential information contained therein to unfairly compete with Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts
3037-7	Exhibit 44: Excerpts from Merck's 2007 Annual Report regarding Fosamax, dated 11/28/2007	Merck's proprietary and/or commercially sensitive internal business practices and databases	Merck would be irreparably harmed if its proprietary and commercially sensitive internal business practices and databases were made public. Merck's competitors could use this information to unfairly compete against Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts

Docket Item	Materials to be Kept Confidential	Legitimate Private or Public Interests Which Warrant Confidentiality	Serious Injury That Would Result Should Order Not Be Entered
3037-8; 3037-9	Exhibit 47: Excerpts from Merck's March 2008 Period Safety Update Report regarding Fosamax, dated 3/10/2008	Merck's proprietary and/or commercially sensitive internal business practices and databases	Merck would be irreparably harmed if its proprietary and commercially sensitive internal business practices and databases were made public. Merck's competitors could use this information to unfairly compete against Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts
3037-10	Exhibit 49: E-mail from Merck's J. Adams to FDA's O. Elekwachi, dated 3/20/2008	Merck's commercially sensitive communications with the FDA	Merck would be irreparably harmed if its confidential communications with the FDA, which includes confidential research data, were available to the public. Its competitors could use the confidential information contained therein to unfairly compete with Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts

Docket Item	Materials to be Kept Confidential	Legitimate Private or Public Interests Which Warrant Confidentiality	Serious Injury That Would Result Should Order Not Be Entered
3037-11	Exhibit 53: E-mail communications between Merck's J. Adams and FDA's J. Marchick, dated 6/24/2008	Merck's commercially sensitive communications with the FDA	Merck would be irreparably harmed if its confidential communications with the FDA, which includes confidential research data, were available to the public. Its competitors could use the confidential information contained therein to unfairly compete with Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts
3037-11	Exhibit 54: E-mail communications between Merck's J. Adams and FDA's J. Marchick, dated 6/30/2008	Merck's commercially sensitive communications with the FDA	Merck would be irreparably harmed if its confidential communications with the FDA, which includes confidential research data, were available to the public. Its competitors could use the confidential information contained therein to unfairly compete with Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts

Docket Item	Materials to be Kept Confidential	Legitimate Private or Public Interests Which Warrant Confidentiality	Serious Injury That Would Result Should Order Not Be Entered
3037-11	Exhibit 55: E-mail and accompanying Regulatory Liaison Telephone Conversation Record, dated 7/8/2008	Merck's commercially sensitive communications with the FDA	Merck would be irreparably harmed if its confidential communications with the FDA, which includes confidential research data, were available to the public. Its competitors could use the confidential information contained therein to unfairly compete with Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts
3037-12	Exhibit 57: Merck's Response to FDA Information Request, dated 7/18/2008	Merck's commercially sensitive communications with the FDA	Merck would be irreparably harmed if its confidential communications with the FDA, which includes confidential research data, were available to the public. Its competitors could use the confidential information contained therein to unfairly compete with Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts

Docket Item	Materials to be Kept Confidential	Legitimate Private or Public Interests Which Warrant Confidentiality	Serious Injury That Would Result Should Order Not Be Entered
3037-12	Exhibit 58: Merck's Response to FDA Information Request, dated 8/6/2008	Merck's commercially sensitive communications with the FDA	Merck would be irreparably harmed if its confidential communications with the FDA, which includes confidential research data, were available to the public. Its competitors could use the confidential information contained therein to unfairly compete with Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts
3037-13; 3037-14; 3037-15; 3037-16; and 3037-17	Exhibit 59: Excerpts from Merck's Prior Approval Supplement, dated 9/15/2008	Merck's commercially sensitive communications with the FDA	Merck would be irreparably harmed if its confidential communications with the FDA, which includes confidential research data, were available to the public. Its competitors could use the confidential information contained therein to unfairly compete with Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts

Docket Item	Materials to be Kept Confidential	Legitimate Private or Public Interests Which Warrant Confidentiality	Serious Injury That Would Result Should Order Not Be Entered
3037-18	Exhibit 60: Excerpts from Merck's 2008 Annual Report regarding Fosamax, dated 11/25/2008	Merck's proprietary and/or commercially sensitive internal business practices and databases	Merck would be irreparably harmed if its proprietary and commercially sensitive internal business practices and databases were made public. Merck's competitors could use this information to unfairly compete against Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts
3037-19	Exhibit 62: Excerpts from Merck's March 2009 Periodic Safety Update Report for Fosamax, dated 3/9/2009	Merck's proprietary and/or commercially sensitive internal business practices and databases	Merck would be irreparably harmed if its proprietary and commercially sensitive internal business practices and databases were made public. Merck's competitors could use this information to unfairly compete against Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts

Docket Item	Materials to be Kept Confidential	Legitimate Private or Public Interests Which Warrant Confidentiality	Serious Injury That Would Result Should Order Not Be Entered
3037-20	Exhibit 65: Regulatory Liaison Telephone Conversation, dated 4/9/2009	Merck's commercially sensitive communications with the FDA	Merck would be irreparably harmed if its confidential communications with the FDA, which includes confidential research data, were available to the public. Its competitors could use the confidential information contained therein to unfairly compete with Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts
3037-21	Exhibit 69: Regulatory Liaison Telephone Conversation Record, dated 5/22/2009	Merck's commercially sensitive communications with the FDA	Merck would be irreparably harmed if its confidential communications with the FDA, which includes confidential research data, were available to the public. Its competitors could use the confidential information contained therein to unfairly compete with Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts

Docket Item	Materials to be Kept Confidential	Legitimate Private or Public Interests Which Warrant Confidentiality	Serious Injury That Would Result Should Order Not Be Entered
3037-21	Exhibit 70: E-mail from Merck's J. Adams to FDA's K. Stiller, dated 6/10/2009	Merck's commercially sensitive communications with the FDA	Merck would be irreparably harmed if its confidential communications with the FDA, which includes confidential research data, were available to the public. Its competitors could use the confidential information contained therein to unfairly compete with Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts
3037-21	Exhibit 71: E-mail from Merck's J. Adams to Merck's Dr. A. de Papp, dated 7/7/2009	Merck's proprietary and/or commercially sensitive internal business practices and databases	Merck would be irreparably harmed if its proprietary and commercially sensitive internal business practices and databases were made public. Merck's competitors could use this information to unfairly compete against Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts

Docket Item	Materials to be Kept Confidential	Legitimate Private or Public Interests Which Warrant Confidentiality	Serious Injury That Would Result Should Order Not Be Entered
3037-22	<p>Exhibit 79:</p> <p>Excerpt from the Worldwide Product Safety Report Generation System Report, dated 9/6/2012</p>	<p>Merck's proprietary and/or commercially sensitive internal business practices and databases</p>	<p>Merck would be irreparably harmed if its proprietary and commercially sensitive internal business practices and databases were made public. Merck's competitors could use this information to unfairly compete against Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Replies to Plaintiffs' Briefs in Response to the Court's Order to Show Cause and in support of its Preliminary Statement of Facts</p>

Docket Item	Materials to be Kept Confidential	Legitimate Private or Public Interests Which Warrant Confidentiality	Serious Injury That Would Result Should Order Not Be Entered
Exhibits to the Declaration of Karen A. Confoy (ECF No. 3153) in Support of Merck's Motion for Summary Judgment Against Plaintiffs (ECF No. 3152)			
3160	<p>Exhibit 3:</p> <p>E-mail from FDA to Merck, dated 6/13/2008</p> <p>This Exhibit was filed under seal pursuant to the June 17, 2013 Sealing Order (ECF No. 232, Civil Action No. 11-cv-05304).</p> <p>This document was Exhibit 4 to Merck's Motion for Summary Judgment Based Upon Federal Preemption (ECF No. 25, Civil Action No. 11-cv-05304), filed January 15, 2013.</p>		

Docket Item	Materials to be Kept Confidential	Legitimate Private or Public Interests Which Warrant Confidentiality	Serious Injury That Would Result Should Order Not Be Entered
3160-1 through 3160-13	<p>Exhibit 4:</p> <p>Letter from Merck to FDA re: Response to Information Request, dated 7/18/2008</p> <p>This Exhibit was filed under seal pursuant to the June 17, 2013 Sealing Order (ECF No. 232, Civil Action No. 11-cv-05304).</p> <p>This document was Exhibit 6 to Merck's Motion for Summary Judgment Based Upon Federal Preemption (ECF No. 25, Civil Action No. 11-cv-05304), filed January 15, 2013.</p>		

Docket Item	Materials to be Kept Confidential	Legitimate Private or Public Interests Which Warrant Confidentiality	Serious Injury That Would Result Should Order Not Be Entered
3160-14 through 3160-22	<p>Exhibit 5:</p> <p>Letter from Merck to FDA re: Prior Approval Supplement, dated 9/15/2008</p> <p>This Exhibit was filed under seal pursuant to the June 17, 2013 Sealing Order (ECF No. 232, Civil Action No. 11-cv-05304).</p> <p>This document was Exhibit 8 to Merck's Motion for Summary Judgment Based Upon Federal Preemption (ECF No. 25, Civil Action No. 11-cv-05304), filed January 15, 2013.</p>		
3161-2	Exhibit 15: Plaintiff Barbara Gaynor's Plaintiff Profile Form	Private and sensitive medical and other information pertaining to Plaintiff Barbara Gaynor	Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Motion for Summary Judgment

Docket Item	Materials to be Kept Confidential	Legitimate Private or Public Interests Which Warrant Confidentiality	Serious Injury That Would Result Should Order Not Be Entered
Exhibits to the Declaration of Karen A. Confoy (ECF No. 3823) and Statement of Material Fact (ECF No. 3824) in Support of Merck's Reply Brief and in Further Support of Its Motion for Summary Judgment Against Plaintiffs (ECF No. 3821)			
3823-1	Exhibit 17: Memorandum to Field Sales Personnel, dated 1/27/2011	Merck's proprietary and/or commercially sensitive internal business practices and databases	Merck would be irreparably harmed if its confidential and proprietary data and other information concerning its internal business practices were available to the public. Its competitors could use the confidential information contained therein to unfairly compete with Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Motion for Summary Judgment
3823-2	Exhibit 18: Internal E-mail from Tina Grasso confirming that merck.com website had been updated with the January 2011 Fosamax Prescribing Information, dated 1/28/2011	Merck's proprietary and/or commercially sensitive internal business practices and databases	Merck would be irreparably harmed if its confidential and proprietary data and other information concerning its internal business practices were available to the public. Its competitors could use the confidential information contained therein to unfairly compete with Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Motion for Summary Judgment

Docket Item	Materials to be Kept Confidential	Legitimate Private or Public Interests Which Warrant Confidentiality	Serious Injury That Would Result Should Order Not Be Entered
3824	Merck's Statement of Material Fact	Merck's Statement of Material Fact contains Merck's proprietary and/or commercially sensitive internal business practices and databases, private and sensitive medical and other information pertaining to Plaintiff Barbara Gaynor, Merck's commercially sensitive communications with the FDA, and nonpublic and unverified information including medical information and personal identifiers regarding non-parties to this litigation for which there is no release for disclosure	Merck would be irreparably harmed if its confidential and proprietary data and other information concerning its internal business practices and/or communications with the FDA were available to the public. Further, its competitors could use the confidential information contained therein to unfairly compete with Merck. Merck requires these Materials to effectively advocate its position and would be irreparably injured if it were precluded from relying upon them in connection with its Motion for Summary Judgment

EXHIBIT B

Below is a list of documents initially, temporarily, filed under seal, as to which Merck no longer requests entry of a sealing order. Merck requests that these documents be unsealed and made publicly available.

Document to be Unsealed and Made Public	Docket Entry
Exhibits to the Declaration of Karen Confoy in Support of Merck's Application for an Order to Show Cause	
<u>Exhibit 4</u> : Letter from Dept. of Health & Human Services to Merck dated 5/22/2009	2859-3
<u>Exhibit 5</u> : E-mail from FDA to Merck dated 4/15/2009	2859-4
Exhibits to the Declaration of David Heubeck in Support of Merck's Replies to Plaintiffs' Procedural Brief in Response to the Court's Order to Show Cause	
<u>Exhibit A-2</u> : Document titled "Draft – CRMSS Data Mining/Proof of Concept Analysis and Results" discussing Merck's efforts to explore the role of data mining in pharmacovigilance and identifies the members of Merck's Data Mining Initiative Committee, dated 6/20/2005	3034
Exhibits to the Declaration of Karen Confoy in Support of Merck's Replies to Plaintiffs' Brief in Response to the Court's Order to Show Cause and in Support of Merck's Preliminary Statement of Facts	
<u>Exhibit 27</u> : WAES Adverse Experience Report 0312USA00476, first sent to the FDA on 12/10/2003	3037-3
<u>Exhibit 39</u> : WAES Adverse Experience Report 0507USA01043	3037-6
<u>Exhibit 66</u> : Regulatory Liaison Telephone Conversation Record dated 4/16/2009	3037-20
Exhibits to the Declaration of Karen Confoy in Support of Merck's Motion for Summary Judgment Against Plaintiffs	
<u>Exhibit 6</u> : Letter from Dept. of Health & Human Services to Merck dated 5/22/2009	3161
<u>Exhibit 12</u> : Letter from FDA to Merck, "Safety Labeling Change and REMS Notification," dated 10/13/2010	3161-1